

Cover Letter

Dear Sir/Madam:

Please find enclosed a Microbial Commercial Activity Notice, submitted on behalf of our client Novozymes North America, Inc. We are submitting the filing via CD Rom.

The submission is titled:

Microbial Commercial Activity Notice (MCAN): Contained Use of a Genetically Modified Microorganism *Trichoderma reesei* for the Biosynthesis of an Enhanced Cellulolytic Protein Preparation. TS MC11BM

The fee was submitted through pay.gov:

Pay.gov Tracking ID: 2542175B

Agency Tracking ID: 74225097900



BIO2011P1

Form Approved. O.M.B. Nos. 2070-0012 and 2070-0038

NON-CBI SUBMISSION

EPA Biotech Form**Biotech Form Report Number**

NOVO110803629877100

Mark (X) if anything is CBI ☐**I. SUBMITTER IDENTIFICATION INFORMATION**CBI ☐

First Name

John

Last Name

Carroll

Position

Staff Specialist

Company

Novozymes North America, Inc.

Mailing Address
(Number & Street)

77 Perry Chapel Road, Box 576

City

Franklinton

State

NC

Postal Code

27525

e-mail

john@novozymes.com

Telephone
(include area code)

919-494-3150

Ia. JOINT SUBMITTER -- If you are submitting this notice as part of a joint submission, mark (X) ☐CBI ☐

First Name

Last Name

Position

Company

Mailing Address
(Number & Street)

City

State

Postal Code

e-mail

Telephone
(include area code)**II. TECHNICAL CONTACT IDENTIFICATION INFORMATION**CBI ☐

First Name

Anthony

Last Name

Pavel

Position

Parntner

Company

K&L Gates, LLP

Mailing Address
(Number & Street)

1601 K Street NW

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State

DC

Postal Code

20006

e-mail

tony.pavel@klgates.com

Telephone
(include area code)

202-778-9089

III. TYPE OF SUBMISSION (Check One)

MCAN (Microbial Commercial Activity Notice)



TERA (TSCA Experimental Release Application)



Tier I Exemption



Tier II Exemption



Biotech TME (Test Market Exemption)

IV. TEXT / COMMENTSCBI ☐

Payment made through pay.gov:

Pay.gov Tracking ID: 2542175B

Agency Tracking ID: 74225097900



BIO2011P2

NON-CBI SUBMISSION

LIST OF ATTACHMENTS

#	Attachment Name	Attachment Filename	Number of Pages	Associated Section Number	CBI
001	Sanitized Novozymes MCAN No TS MC11MB Recombinant T reesei strain	Sanitized MCAN_No_TS_MC11MB_Reco	40		
002	Appendix A-Metabolite potential of T reesei	Appendix A-Metabolite potential of T reesei.pdf	9		
003	Appendix B- Production of Food Additives using Filamentous Fungi	Appendix B- Production of Food Additives using Filamentous	15		
004	Sanitized - Appendix C -Toxicity Study by Oral Gavage Administration to CD Rats for 28 Days --	Appendix C - Sanitized - Toxicity Study by Oral Gavage	93		
005	Sanitized - Appendix D -Test for Mutagenic Activity Ames test -- Study Report	Appendix D - Sanitized - Test for Mutagenic Activity Ames test --	28		
006	Sanitized - Appendix E -Invitro Cytotoxicity Test - Study Report	Appendix E - Sanitized - Invitro Cytotoxicity Test -- Study	10		
007	Sanitized - Appendix F - Assessment of Ready Biodegradability Study Report	Appendix F - Sanitized - Assessment of Ready	27		
008	Sanitized - Appendix G - Acute Toxicity to Daphnia magna -- Study Report	Appendix G - Sanitized - Acute Toxicity to Daphnia magna --	30		
009	Sanitized - Appendix H - Acute Toxicity to Fish -- Study Report	Appendix H - Sanitized - Acute Toxicity to Fish -- Study	31		
010	Sanitized - Appendix I - Algal Growth Inhibition Assay -- Study Report	Appendix I - Sanitized - Algal Growth Inhibition Assay -- Study	34		

Mark (X) this box if the data continues on the next page.

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ATTACHMENT HEADER SHEET

Attachment Number 001

Attachment Name

Sanitized Novozymes MCAN No TS MC11MB Recombinant T reesei strain

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

NOVO110803629877100

ATTACHMENT HEADER SHEET

Attachment Number 002

Attachment Name

Appendix A-Metabolite potential of *T. reesei*

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

NOVO110803629877100

ATTACHMENT HEADER SHEET

Attachment Number 003

Attachment Name

Appendix B- Production of Food Additives using Filamentous Fungi

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

NOVO110803629877100

ATTACHMENT HEADER SHEET

Attachment Number 004

Attachment Name

Sanitized - Appendix C -Toxicity Study by Oral Gavage Administration to CD Rats for 28 Days -- Study Report

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

NOVO110803629877100

ATTACHMENT HEADER SHEET

Attachment Number 005

Attachment Name

Sanitized - Appendix D -Test for Mutagenic Activity Ames test -- Study Report

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

NOVO110803629877100

ATTACHMENT HEADER SHEET

Attachment Number 006

Attachment Name

Sanitized - Appendix E -Invitro Cytotoxicity Test -- Study Report

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

NOVO110803629877100

ATTACHMENT HEADER SHEET

Attachment Number 007

Attachment Name

Sanitized - Appendix F - Assessment of Ready Biodegradability Study Report

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

NOVO110803629877100

ATTACHMENT HEADER SHEET

Attachment Number 008

Attachment Name

Sanitized - Appendix G - Acute Toxicity to Daphnia magna -- Study Report

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

NOVO110803629877100

ATTACHMENT HEADER SHEET

Attachment Number 009

Attachment Name

Sanitized - Appendix H - Acute Toxicity to Fish -- Study Report

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

NOVO110803629877100

ATTACHMENT HEADER SHEET

Attachment Number 010

Attachment Name

Sanitized - Appendix I - Algal Growth Inhibition Assay -- Study Report

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

NOVO110803629877100